Evaluating the Clinical Trial Option GUIDE TO INFORMED CONSENT

INTRODUCTION

Informed Consent is a voluntary agreement to participate in research. It is not just a form that is signed — *it is a process,* in which the child or their parent/guardian has an understanding of the research and its risks.

During the informed consent process, the research team will explain the key elements of the study and what you or your child's participation will involve.

Whether or Not to Participate is Your Decision

Participation in any trial is voluntary. The Informed Consent document should make clear that participating in clinical trials is voluntary and you have the right not to participate, or to end your participation in the trial at any time. It will also include a statement informing you that the Principal Investigator can discontinue the trial at any time.

The document should include a copy of the Research Subject's Bill of Rights. You should be given a copy of the Informed Consent to keep.

Understand the Risks of Participation AND Your Willingness to Accept Them

At the beginning of a clinical trial, it is often not yet known whether or not the new treatment will help your child. Likewise, it may not be known if the new treatment will cause serious side effects. When weighing the risks and potential outcomes, you should keep in mind that the treatment may or may not benefit your child.

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You Have Time to Read and Consider It Carefully

The Informed Consent Document can be overwhelming. Researchers or the Trial Coordinators should give you the time you need to ask questions about any information you don't understand or find confusing. *Take your time and read the document carefully*. **You should not** *feel pressured to sign*.

Questions to Ask

- Who is the Principal Investigator?
- Who is sponsoring the trial?
- What phase is this trial in? (Different phases mean different stages of research including never tested in)
- If the trial is beyond a Phase I, what did the research investigators learn from that trial and how has it affected the current trial?
- What tests and procedures will be performed as part of the trial?
- What is the expected length of the trial?
- What are the risks to my child? What is the likelihood the risks will occur? What are the possible benefits expected from the trial?
- What are the alternative procedures or treatments outside of the trial that my child might benefit from?
- What other trials for the same disease are currently underway? How is this treatment different from the other treatments?
- How will my child's medical information be kept confidential?
- What will happen if injury happens to my child during the trial?
- What occurrences might end my child's participation in the trial?
- Are there any expenses I might personally be responsible for?

For more information about Informed Consent visit:

https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials

CONCLUSION

Considering clinical trial is a process. Participation is your choice. You have a right to ask questions and to seek advice. And remember: only you are allowed to make the decision.

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